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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/560,322	09/12/2006	Birgit Baumgarten	4-33201A	4964
75074	7590	05/05/2009		
NOVARTIS INSTITUTES FOR BIOMEDICAL RESEARCH, INC. 220 MASSACHUSETTS AVENUE CAMBRIDGE, MA 02139			EXAMINER LI, RUIXIANG	
			ART UNIT	PAPER NUMBER
			1646	
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			05/05/2009	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/560,322	BAUMGARTEN ET AL.	
	Examiner	Art Unit	
	RUIXIANG LI	1646	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 06 March 2009.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-15 is/are pending in the application.
- 4a) Of the above claim(s) 5,6 and 10-15 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-4 and 7-9 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☒ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date _____ | 6) <input checked="" type="checkbox"/> Other: <u>Sequence alignment</u> |

DETAILED ACTION

Restriction/Election

1. Applicant's election without traverse of Group I (claims 1-4 and 7-9) and SEQ ID NO: 3 in the reply filed on 03/06/2009 is acknowledged.
2. Claims 1-15 are pending. Claims 1-4 and 7-9 are currently under consideration. All other claims are withdrawn from further consideration pursuant to 37 CFR 1.142(b), as being drawn to a nonelected invention, there being no allowable generic or linking claim. Election was made **without** traverse in the reply filed on 03/06/2009.

Objection to Oath/Declaration

3. The oath/declaration is objected to because the filing date for the priority document, 60/480,245, is inaccurate; the correct filing date is "20/06/2003", not "30/06/2003".

Objection to the Disclosure

4. The disclosure is objected to because it contains an embedded hyperlink (page 26, the 3rd paragraph). Applicant is required to delete the embedded hyperlink. See MPEP § 608.01.

Claim Rejections—35 USC § 112, 1st paragraph

5. The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the

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art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

6. Claims 1, 2, and 7-9 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventors, at the time the application was filed, had possession of the claimed invention.

To provide adequate written description and evidence of possession of a claimed genus, the specification must provide sufficient distinguishing identifying characteristics of the genus. The factors to be considered include disclosure of complete or partial structure, physical and/or chemical properties, functional characteristics, structure/function correlation, methods of making the claimed product, or any combination thereof.

The elected invention of claims 1, 2, and 7-9 are drawn to the use of an isolated proton-sensing GPCR polypeptide in the development of a medicament for disease and medical conditions in which proton homeostasis is imbalanced and a method for screening to identify compounds that agonize or antagonize the proton-sensing activity of an isolated proton-sensing GPCR polypeptide having at least 20% identity to the polypeptide of SEQ ID NO: 3. The claims do not require that the proton-sensing GPCR polypeptides possess any particular any particular conserved structure nor other disclosed distinguishing feature. Thus, the claims are drawn to a genus of proton-sensing GPCR polypeptides without any structural features.

The instant disclosure of a human GPR4 polypeptide of SEQ ID NO: 3 does not adequately support the scope of the recited genus, which encompasses a

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substantial variety of subgenera including full-length genes. A description of a genus of cDNA may be achieved by means of a recitation of a representative number of cDNAs, defined by nucleotide sequence, falling within the scope of the genus, or of a recitation of structural features common to the genus, which features constitute a substantial portion of the genus. *Regents of the University of California v. Eli Lilly & Co.*, 119 F3d 1559, 1569, 43 USPQ2d 1398, 1406 (Fed. Cir. 1997). The instant disclosure fails to provide sufficient description information, such as definitive structural features of the recited genus of proton-sensing GPCR polypeptides. There is no description of the conserved regions that are critical to the structure and function of the genus. There is no description of the sites at which variability may be tolerated and there is no information regarding the relation of structure to function.

While teaching a human GPR4 polypeptide (see, e.g., Mahadevan et al., *Genomics* 30:84-88, 1995; Yang et al., US Patent No. 6,919,176 B2), the prior art does not provide compensatory structural or correlative teachings to enable one skilled in the art to identify the encompassed polypeptides as being identical to those instantly claimed.

Moreover, claim 9, (b), recites "a labelled competitor". However, the specification fails to disclose any labelled competitors that bind to the proton-sensing GPCR polypeptides.

Due to the breadth of the recited genus and lack of the definitive structural features of the recited genus, one skilled in the art would not recognize from the

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disclosure that the applicant was in possession of the genus of proton-sensing GPCR polypeptides and thus the instantly claimed method.

Claim Rejections—35 USC § 112, 2nd paragraph

7. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

8. Claims 1-4 and 7-9 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite. Claims 1-4, 7, and 8 provide for the use of an isolated proton-sensing GPCR polypeptide, but, since the claim does not set forth any steps involved in the method/process, it is unclear what method/process applicant is intending to encompass. A claim is indefinite where it merely recites a use without any active, positive steps delimiting how this use is actually practiced.

Claims 1-4, 7, and 8 are rejected under 35 U.S.C. 101 because the claimed recitation of a use, without setting forth any steps involved in the process, results in an improper definition of a process, i.e., results in a claim which is not a proper process claim under 35 U.S.C. 101. See for example *Ex parte Dunki*, 153 USPQ 678 (Bd.App. 1967) and *Clinical Products, Ltd. v. Brenner*, 255 F. Supp. 131, 149 USPQ 475 (D.D.C. 1966).

Claim 2 is indefinite because it refers to the commercial databases.

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Claim 9 is indefinite because it recites the indefinite language “using detection systems appropriate to the cells...” (step (c)), “using for instance” at the end of the claim (step (d)). The use of such ambiguous language renders the claim indefinite.

Claim Rejections—35 USC § 102 (e)

9. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

10. Claims 7 and 8 are rejected under 35 U.S.C. 102(e) as being anticipated by Yang et al. (US Patent No. 6,919,176 B2, Jul. 19, 2005; 102(e) date: May 7, 2001).

Yang et al. teach a human G-protein coupled receptor 4 (GPR4) that is 98.7% identical to the amino acid sequence set forth in SEQ ID NO: 3 (see attached sequence alignment). Yang et al. also teach screening assays for determining inhibitors and activators of the GPCR that can be used as therapeutics (column 33, the 2nd paragraph; column 35; column 37, the 2nd paragraph). Such an inhibitor and activator are capable of agonizing or antagonizing the proton-sensing activity of the polypeptide of SEQ ID NO: 3. Thus, the teachings of Yang et al. meet the limitations of claims 7 and 8.

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11. Claims 7-9 are rejected under 35 U.S.C. 102(e) as being anticipated by Logan et al. (US 2003/0109044 A1, June 12, 2003; 102(e) date: Oct. 16, 2001).

Logan et al. teach a human G-protein coupled receptor, 279, which is 98.7% identical to the amino acid sequence set forth in SEQ ID NO: 3 (see attached sequence alignment). Logan et al. teach screening assays for identifying modulators that bind to 279 receptor or have a stimulatory or inhibitory effect on 279 receptor expression or activity (page 24, paragraph [0282]).

Logan et al. teach a cell based assay in which a cell expressing a 279 receptor is contacted with a test compound and the ability of the test compound to modulate the activity of 279 receptor is determined by monitoring biological messengers or signaling to G proteins (page 25, paragraph [0288]). Logan et al. teach the ability of a test compound to modulate 279 receptor binding to a compound, e.g., a 279 receptor substrate, or to bind to 279 receptor can be determined by coupling the compound, e.g., a 279 receptor substrate, with a radioisotope or an enzymatic label such that binding of the compound, e.g., a substrate to 279 receptor, can be determined by detecting the labeled compound, e.g., a substrate, in a complex (page 25, paragraph [0290]). Logan et al. also teach a cell-free assay which includes contacting the 279 receptor with a known compound that binds the 279 receptor to form an assay mixture, contacting the assay mixture with a test compound, and determining the ability of the test compound to interact with a 279 receptor (page 26, paragraph [0303]).

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Since the 279 receptor is 98.7% identical to the amino acid sequence set forth in SEQ ID NO: 3, an inhibitor and activator identified by the method Logan et al. are capable of agonizing or antagonizing the proton-sensing activity of the polypeptide of SEQ ID NO: 3. Thus, the teachings of Logan et al. meet the limitations of claims 7-9.

Claim Objection—Minor Informalities

12. Claims 1-4 and 7-9 are objected to because they recite non-elected subject matter (amino acid sequences other than elected SEQ ID NO: 3). Appropriate correction is required.

Conclusion

13. No claims are allowed.

Advisory Information

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Ruixiang Li whose telephone number is (571) 272-0875. The examiner can normally be reached on Monday through Friday from 8:30 am to 5:00 pm. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Gary Nickol, can be reached on (571) 272-0835. The fax number for the organization where this application or proceeding is assigned is (571) 273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, please contact the Electronic Business Center (EBC) at the toll-free phone number 866-217-9197.

/Ruixiang Li/

Primary Examiner, Art Unit 1646

Ruixiang Li, Ph.D.

May 4, 2009